PATENT COOPERATION TREATY

From the Japan Patent Office

(INTERNATIONAL SEARCHING AUTHORITY)

PCT

To: Agent of Applicant
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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43-2.1)

	Date of mailing *(day/month/year)* 24.8.2004
Applicant's or agent's file reference 09651	For Further Action see paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/JP2004/008471	10.06.2004	10.06.2003

International Patent Classification (IPC) Int. Cl.[7] G01N33/53

Applicant
DAINIPPON PHARMACEUTICAL CO., LTD.

1. This report contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43-2.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. Further Action

If a demand for international preliminary examination is made, this written opinion is the first drawn up by the International Preliminary Examining Authority (IPEA) except that this does not apply where the Applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1 bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Established this written opinion
10.08.2004

Name and mailing address	Authorized officer	2J	9217
Japan Patent Office (ISA/JP) 4-3, Kasumigaseki 3-chome Chiyoda-ku, Tokyo 100-8915 Japan	Examiner Shoko Yamamura Telephone No. 03-3581-1101 extension 3251		

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

Intern. application No.PCT/JP2004/008471

I. Basis of the opinion

1. Unless otherwise indicated under this item, this written opinion was drawn up based on the language in which the international application was filed.

[ ] This written opinion is in the following language_____which is:
The language of a translation furnished for the purposes of the international search (under Rule 12.3 and 23.1 (b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of

a. type of material
- ☐ a sequence listing
- ☐ table(s) related to the sequence listing

b. format of material
- ☐ on paper
- ☐ in electronic form

c. time of filing/furnishing
- ☐ contained in the international application in written form
- ☐ filed together with the international application in computer readable form
- ☐ furnished subsequently to this Authority for the purposes of search

3. In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

Intern. application No.PCT/JP2004/008471

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step, or to be industrially applicable have not been examined in respect of:

☐ the entire international application,
☒ claims Nos. 22 and 23

because:

☒ the said international application, or the said claim No(s). 22 and 23 relate to the following subject matter which does not require an international preliminary examination (specify):

The invention described in claims 22 and 23 is that of a commercial method and an advertising method and consequently falls under methods of business activities. Claims 22 and 23 relates to a subject matter which does not require an international preliminary examination by the International Preliminary Examining Authority under PCT rule 67.1 (iii).

☐ the description, claims or drawings (indicate particular elements below) or said claims Nos. is (are) so unclear that no meaningful opinion could be formed (specify):

☐ the claims or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 22 and 23

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C (guideline for preparing specification etc containing base sequence and/or amino acid sequence) of the Administrative Instructions In that:

the written form
☐ has not been furnished
☐ does not comply with the standard

the computer readable form
☐ has not been furnished
☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ have not been furnished
☐ do not comply with the technical requirements

☐ See separate sheet for further details.

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

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V. Reasoned statement under Rule 43-2.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	2-7, 10, 11, 13-15, 17-21, 25	YES
	Claims	1, 8, 9, 12, 16, 24	NO
Inventive Step (IS)	Claims	2-7, 10, 11, 13-15, 17-21, 25	YES
	Claims	1, 8, 9, 12, 16, 24	NO
Industrial Applicability (IA)	Claims	1-21, 24-25	YES
	Claims		NO

2. Citations and Explanations

Reference 1: CHEST Vol.123, No.5 (May 2003) p.1375-1378

Claims 1, 8, 9, 12, 16 and 24

Reference 1 describes measurement of the D-dimer level in patients suspected to have acute aortic dissection, and describes that, as a result of the aforementioned measurement, all acute aortic dissection patients turned positive in a D-dimer test, the measurement of D-dimer is expected to be an essential element for the initial evaluation of patients suspected to have aortic dissection, and, as a measurement method of D-dimer, a latex wherein a specific monoclonal antibody specific to D-dimer is bound is used for the measurement.

The invention relating to claims 1, 8, 9, 12, 16 and 24 is described in Reference 1 and lacks novelty.

Claims 2-7, 10, 11, 13-15, 17-21 and 25

Determination of the onset of Stanford type A acute aortic dissection, Stanford type B acute aortic dissection or acute myocardial infarction, based on the measurement of the D-dimer concentration, is not described in any of the references cited in the International Search Report, nor is it obvious to those of ordinary skill in the art.